THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[LL 974] NOVEMBER 2017 **Sub. Code: 2974**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code : 262974

Time : Three hours **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. a) What is mean by Randomization? How Randomization is done in clinical trial? Give its significance in clinical trial.
   b) Explain the method, merits and demerits of Randomization with example.

2. Name the essential documents required for filing during clinical trial. Explain the structure and content of these documents.

II. Write notes on: **(7 x 5 = 35)**

1. Briefly write on drug safety reporting method.

2. What are the ethical guidelines to conduct clinical trials in children?

3. Write the functions of IRB.

4. How study site has been selected? Explain.

5. As per informed consent, what are the points to be explained to the patients while registering for clinical trial?

6. What act has been considered as fraud and misconduct according to US FDA in clinical trial?

7. What are the documents to be audited during clinical trial audit?

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[LM 974] MAY 2018 **Sub. Code: 2974**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code : 262974

Time : Three hours **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Write the composition, member's responsibilities, functions and challenges of IRB.

2. Explain the essential features of an investigational brochure of a clinical trial.

II. Write notes on: **(7 x 5 = 35)**

1. Write the indicators of a health outcome measures as per Indian health policy.

2. Define the term:
   a) Cohort study b) Retrospective study c) Double blind study
   d) Placebo e) Cross sectional study

3. How clinical trial study has been initiated in a site? Explain the regulatory requirements.

4. Write the composition and functions of safety reporting committee.

5. How data system has been validated?

6. Briefly write on data mining.

7. Explain the methods of archival.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[LN 974] NOVEMBER 2018 **Sub. Code: 2974**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code : 262974

Time : Three hours **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Explain the filing procedure, documents required and approval process of IND application.

2. a) What is mean by routine audit? Who will conduct? Write the difference between audit and inspection.
   b) Write in two sentences about the terminology used in clinical trials.
      i) Source data ii) Quality improvement
      iii) Data quality management iv) Data monitoring plan
      v) Data cleaning

II. Write notes on: **(7 x 5 = 35)**

1. Briefly write on post marketing surveillance.
2. What is bioequivalence study? How it is conducted?
3. What are the responsibilities of an investigator?
4. What do you understand by accountability and reconciliation of document maintenance pertaining to clinical trial?
5. Briefly write on close out visit report content.
6. Explain case report sheet of clinical trial.
7. What is meant by informed content? Write the essential features of informed consent.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[LO 974] MAY 2019 **Sub. Code: 2974**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
BRANCH V – PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code : 262974

Time : Three hours **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Define clinical trials. Discuss in detail five various phases involved in drug development process.

2. a) Define investigational new drug application and describes the component and categories of investigational new drug application.
   b) What are the essential documents for the conducting of clinical trials and its purpose?

II. Write notes on: **(7 x 5 = 35)**

1. Significance of post marketing surveillance.
2. Study designs in a clinical trial.
3. Vulnerable subjects.
4. Define the followings:
   a) Blinding b) Comparator c) Good clinical practice
5. Data migration and archiving.
6. Write a note on schedule Y.
7. Good clinical practice and its principles.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[LP 974] NOVEMBER 2019 **Sub. Code: 2974**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
BRANCH IV – PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code : 262974

Time : Three hours **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. a) Explain the components of clinical research protocol and the process of protocol preparation.
   b) Discuss in detail about various methods used in post marketing safety monitoring process.

2. a) Define Bias. Discuss in detail about various sources of bias and methods to avoid Bias.
   b) Describe in detail about regulatory setup that governs the clinical research process in India.

II. Write notes on: **(7 x 5 = 35)**

1. Write the responsibilities of sponsor's in clinical trial.
2. Write a short note on drug discovery process.
3. List the type of audits and its importance in clinical trials.
4. Role and responsibilities of data management team in clinical trials.
5. Preparation of Informed Consent Form (ICF).
6. Explain briefly the ICH guidelines.
7. Briefly write on Case Report Form.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[LQ 0121] **JANUARY 2021** **Sub. Code: 2974**

(APRIL 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION

SEMESTER-I (PCI New regulations 2016)

PHARMACY PRACTICE - MPP

PAPER IV – CLINICAL RESEARCH

Q.P. Code : 262974

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. What is ethical committee? Explain its constitution, function and challenges in the implementation of ethical guidelines.

2. What are clinical trial documents? Explain the various documents with its guidelines to prepare.

II. Write notes on: **(7 x 5 = 35)**

1. What is drug discovery? Explain the various approaches to drug discovery.
2. After study enrollment, a subject met with an accident and admitted in the hospital. In this situation - what will be the responsibility of study coordinator and investigator?
3. Describe the different sampling methods in clinical research.
4. If you are a clinical trial auditor and during the audit if you find some of the misconduct in study site, what will be your audit report and follow-up?
5. Procurement and storage of investigation product.
6. ICMR guideline in conduct of clinical trials.
7. Describe the electronic data capturing system.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[MPHARM 0921] SEPTEMBER 2021 Sub. Code: 2974
(OCTOBER 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-I (PCI New regulations 2016)
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH
Q.P. Code : 262974

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. What is clinical trial? Explain the various phases of clinical trials with examples.
2. Write the composition, member's responsibilities, functions and challenges of IRB.

II. Write notes on: **(7 x 5 = 35)**

1. Briefly write on post marketing surveillance.
2. Good Clinical Practice and its principles.
3. Vulnerable subjects.
4. Roles and responsibilities of Investigator.
5. Preparation of Informed Consent Form (ICF).
6. Write a note on schedule Y.
7. What is bioequivalence study? How it is conducted?

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[MPHARM 0422] APRIL 2022 Sub. Code: 2974
(OCTOBER 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-I (PCI New regulations 2016)
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH
Q.P. Code : 262974

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Define investigational new drug application and describes the component and categories of investigational new drug application.

2. What are the various Ethical issues in biomedical research? Explain in detail about various guidelines to be followed in the preparation of the study protocols.

II. Write notes on: **(7 x 5 = 35)**

1. List the type of audits and its importance in clinical trials.
2. Briefly write on Case Report Form.
3. Data migration and archiving.
4. Briefly write on close out visit report content.
5. What are the responsibilities of an investigator?
6. What do you understand by accountability and reconciliation of document maintenance pertaining to clinical trial?
7. Write the composition and functions of safety reporting committee.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 0922] **SEPTEMBER 2022** **Sub. Code: 2974**
(APRIL 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New regulations 2016)
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code : 262974

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. What is clinical trial audit? Explain the audit process, follow up documentation and fraud and misconduct management.

2. Explain ICH GCP and ICMR guidelines in conduct of clinical trials.

II. Write notes on: **(7 x 5 = 35)**

1. Randomization techniques.
2. Various phases of clinical trials
3. Roles and responsibilities of Monitor.
4. Health outcome measures.
5. Bioequivalence Studies.
6. Study close-out visit preparation and report.
7. Data mining and warehousing.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 0423] APRIL 2023 Sub. Code: 2974
(OCTOBER 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New regulations 2016)
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code: 262974

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. What is clinical trial data management? Explain the standard operation procedures, data management in Clinical data management.

2. What do you mean by Research Design? Explain in detail about various types of Research design with examples.

II. Write notes on: **(7 x 5 = 35)**

1. Difference between cohort study and case control study.
2. Drug safety reporting.
3. Roles and responsibilities of a Contract Research Organization.
4. Informed consent form.
5. Electronic data capture systems.
6. Review of source documents.
7. Investigators brochure.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 0823] **AUGUST 2023** **Sub. Code: 2974**
(APRIL 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code: 262974

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Explain in detail about various Quality Assurance and Quality Control procedures involved in clinical trials.

2. What is clinical research? Explain the planning and execution of clinical trials and add the notes on essential documents needed to initiate clinical trial.

II. Write notes on: **(7 x 5 = 35)**

1. Investigational new drug application.
2. Briefly explain the sampling methods.
3. Roles and responsibilities of sponsor.
4. Site/ investigator selection.
5. What is CRF? Details the CRF.
6. Clinical trial audit.
7. Quality control and quality assurance in CDM.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 1223] DECEMBER 2023 Sub. Code: 2974
(OCTOBER 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code: 262974

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. A) What is clinical trial? Explain the various phases of clinical trials.
   B) In a clinical trial, one of study subjects named Mr. X is hospitalized for the complaints of sudden collapse. In this situation what will be the procedure and responsibilities of investigator, study coordinator, sponsor and contract research organizations.

2. Explain the various clinical trial start up activities in the order of undertaking.

II. Write notes on: **(7 x 5 = 35)**

1. Describe the investigational new drug application submission.
2. What is study close-out visit? Discuss the documents and procedures involved in the close-out visit.
3. What is clinical trial audit? Discuss the types of process of audits.
4. Quality control and quality assurance in clinical data management.
5. ICH – GCP guidelines in the conduct of clinical trials.
6. What all are the essential documents for clinical trial?
7. Discuss with example the case report form.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 0524] MAY 2024 Sub. Code: 2974
(APRIL 2024 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code: 262974

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. A) Explain the Pharmacological and Toxicological approaches to Drug discovery.
   B) Describe the roles and responsibilities of Investigators and Clinical Research associates.

2. A) What is Institutional human ethical committee? Give the composition, qualification required for the members and explain the functions of the committee.
   B) Discuss the roles and responsibilities of auditors in clinical research.

II. Write notes on: **(7 x 5 = 35)**

1. Write in detail about the central drug standard control organization guidelines.
2. Explain briefly the informed consent process.
3. Explain: a) Placebo b) Human Subjects c) Candidate drug.
4. What are the major challenges observed in implementation of the regulatory guidelines in clinical trials?
5. Post marketing surveillance.
6. Source documents in clinical trial.
7. Write the significance of preclinical testing in clinical research.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 0425] **APRIL 2025** **Sub. Code: 2974**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code: 262974

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. a) Elaborate on randomization techniques involved in the selection of subjects.
   b) Discuss on sampling methods involved in clinical trial process.

2. Explain various types of audits involved in the clinical trial process and write the significance of conducting audit.

II. Write notes on: **(7 x 5 = 35)**

1. Enumerate on the drug discovery and development process.
2. Write a note on challenges in obtaining informed consent.
3. Define investigators brochure and describe its contents.
4. Write a note on procurement and storage of investigational product.
5. Enumerate on various responsibilities of clinical research associate.
6. Write a note on ICMR guideline in conduct of clinical trial process.
7. Describe about the close out process of clinical trial.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 1025] **OCTOBER 2025** **Sub. Code: 2974**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACY PRACTICE - MPP
PAPER IV – CLINICAL RESEARCH

Q.P. Code: 262974

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Discuss in detail on the process of conducting clinical trial visit at the investigational site and write about the reports to be prepared on the visit.

2. Explain in detail about conduct if various phases of clinical trials with their limitations.

II. Write notes on: **(7 x 5 = 35)**

1. Enumerate on the constitution and responsibilities of institutional review board.
2. Write a note on various meetings conducted during clinical trial and write its significance.
3. Define case report form. Describe the contents and its significance.
4. Describe the role and significance of data management in clinical trials.
5. Explain the components involved in FDA inspections.
6. Write in brief about the drug safety reporting and its importance.
7. Describe the role and responsibilities of monitors in clinical trials.

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